

(4) Device manufacture date (month, day, year);

(5) Was device labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA "Coding Manual for Form 3500A");

(7) Whether remedial action was taken and type;

(8) Whether use of device was initial, reuse, or unknown;

(9) Whether remedial action was reported as a removal or correction under section 519(f) of the act (list the correction/removal report number); and

(10) Additional manufacturer narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or distributor report, including missing event codes, or information corrected on such forms after manufacturer verification;

(ii) For each event code provided by the user facility under §803.32(d)(10) or a distributor, a statement of whether the type of the event represented by the code is addressed in the device labeling; and

(iii) If any required information was not provided, an explanation of why such information was not provided and the steps taken to obtain such information.

§803.53 Five-day reports.

A manufacturer shall submit a 5-day report to FDA, on Form 3500A or electronic equivalent as approved by FDA under §803.14 within 5 workdays of:

(a) Becoming aware that a reportable MDR event or events, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or

(b) Becoming aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. The time period stated in the original written request can be extended by FDA if

it is in the interest of the public health.

§803.55 Baseline reports.

(a) A manufacturer shall submit a baseline report on FDA Form 3417, or electronic equivalent as approved by FDA under §803.14 for a device when the device model is first reported under §803.50.

(b) Each baseline report shall be updated annually, on the anniversary month of the initial submission, after the initial baseline report is submitted. Changes to baseline information shall be reported in the manner described in §803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). Baseline reports shall contain the following:

(1) Name, complete address, and registration number of the manufacturer's reporting site. If the reporting site is not registered, FDA will assign a temporary registration number until the reporting site officially registers. The manufacturer will be informed of the temporary registration number;

(2) FDA registration number of each site where the device is manufactured;

(3) Name, complete address, and telephone number of the individual who has been designated by the manufacturer as its MDR contact and date of the report. For foreign manufacturers, a confirmation that the individual submitting the report is the agent of the manufacturer designated under §803.58(a) is required;

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code and any other product identification number or designation;

(5) Identification of any device previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported, including the identification of the previously reported device by model number, catalog number or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including 510(k) premarket notification number

or PMA number, if applicable, and whether the device is currently the subject of an approved post-market study under section 522 of the act;

(7) Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device;

(8) Shelf life, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and, an estimate of the number of devices in current use; and

(10) Brief description of any methods used to estimate the number of devices distributed and the method used to estimate the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

EFFECTIVE DATE NOTE: At 61 FR 39869, July 31, 1996, in §803.55, paragraphs (b)(9) and (10) were stayed indefinitely.

§803.56 Supplemental reports.

When a manufacturer obtains information required under this part that was not provided because it was not known or was not available when the initial report was submitted, the manufacturer shall submit to FDA the supplemental information within 1 month following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H-2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

(c) For reports that cross reference previous reports, include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s).

§803.57 Annual certification.

(a) All manufacturers required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under §803.14. The date for submission of certification coincides with the date for the firm's annual registration, as designated in §807.21 of this chapter. Foreign manufacturers shall submit their certification by the date on which they would be required to register under §807.21 of this chapter if they were domestic manufacturers. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The manufacturer shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A manufacturer may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or manufacturing sites owned by the firm. In this circumstance, the firm may designate more than one certifying official, each of whom will sign a certification statement pertaining to his/her respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the reporting site and whether the firm is a manufacturer;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for each manufacturing site covered by the certification and the number of reports submitted for devices manufactured at each site;